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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,366	09/26/2006	Arthur E. Uber III	IN/04-002PCT.US	7429
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GREGORY L. BRADLEY MEDRAD INC ONE MEDRAD DRIVE INDIANOLA, PA 15051			EXAMINER LEE, BENJAMIN HYOUNGSOI	
			ART UNIT 3739	PAPER NUMBER
			MAIL DATE 01/29/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/599,366

Applicant(s)

UBER ET AL.

Examiner

BENJAMIN LEE

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 1-17, 21-29, 45-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-20, 30-44 and 51-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date 8/29/07, 11/21/08

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of species 2 in the reply filed on 1/6/2010 is acknowledged. Applicant has not supplied a ground of traversal. Therefore the traversal is not persuasive.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the feature where the "penetrator comprises an axial passage therethrough in which the tissue resident conduit is positioned during penetration" (in claim 38) together with the parent limitations of 37 and 34 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

2. **Claim 54** is objected to because of the following informalities: Claim 54 recites "the at least two point". This should be amended to "the at least two points". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claim 44** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 44 recites the limitation "the effector" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 18, 20, 30-36, 42 and 44** are rejected under 35 U.S.C. 102(b) as being anticipated by Rizioiu et al. (USPN 6,669,685).

As to claim 18, Rizioiu discloses a device for penetrating tissue and positioning a catheter, comprising: a catheter (Fig. 3, col. 2, lines 58-61) comprising a passage therethrough (see Fig. 3); and a penetrator in operative connection with the catheter (e.g. distal end of catheter comprising fiber optic guide 61, air tube 63 and water tube 65 which in combination cut/penetrate tissue, col. 5, lines 7-19), the penetrator being energized in a repetitive manner to assist in penetrating tissue (col. 6, lines 39-47).

As to claim 20, Rizioiu discloses another embodiment where the penetrator is positioned on the exterior of the catheter (see Fig. 4a).

As to claim 30, Rizioiu discloses a method of inserting a tissue resident conduit (e.g. catheter/cannula of Fig. 9b) into tissue, comprising the step: energizing at least a portion of a forward end of the conduit insertion device to assist in penetrating tissue (Fig. 9b, col. 10, lines 48-50).

As to claim 31, Rizioiu discloses the tissue resident conduit is a catheter (col. 2, lines 58-60).

As to claim 32, Rizioiu discloses the tissue resident conduit is flexible (col. 13, lines 28-30).

As to claim 33, Rizioiu discloses the tissue resident conduit has a blunt forward surface (see Fig. 3).

As to claim 34, Rizioiu discloses a device in Fig. 9b for inserting a tissue resident conduit (e.g. cannula/catheter of Fig. 9b) comprising: at least one component (e.g. fiber optic guide 132) that is energized during penetration to assist in penetrating tissue (abstract).

As to claim 35, Rizioiu discloses the tissue resident conduit is flexible (col. 13, lines 28-30) and the energized component is positioned on a forward end of the tissue resident conduit (see Fig. 9b).

As to claim 36, Rizioiu discloses a mechanism (e.g. delivering electromagnetic energy via a fiber optic guide, col. 7, lines 20-23) which directs the penetration of the tissue resident conduit (e.g. the placement/orientation of the distal portion of the fiber optic guide generally directs penetration of the tissue resident conduit to that direction).

As to claim 42, the tissue resident conduit is a catheter since it's a tube inserted into the body and is capable of removing fluid from the body and is capable of keeping a passage open.

As to claim 44, Rizioiu discloses the effector is capable of penetrating through a wall of a blood vessel since it provides cutting operations on vessels (col. 2, lines 25-30).

5. **Claims 18-19, 34, 37, 39-41 and 43** are rejected under 35 U.S.C. 102(b) as being anticipated by Cosman et al. (USPN 6,478,793).

As to claim 18, Cosman discloses a device in Fig. 3 for penetrating tissue and positioning a catheter comprising: a catheter 142 comprising a passage therethrough (see Fig. 3); and a penetrator 184 in operative connection with the catheter (col. 7, lines 29-35), the penetrator being energized in a repetitive manner to assist in penetrating tissue (col. 3, lines 66-67).

As to claim 19, Cosman discloses the penetrator is removably positioned within the passage of the catheter since the catheter accepts various types of penetrators (col. 7, lines 32-35).

As to claim 34, Cosman discloses a device in Fig. 3 for inserting a tissue resident conduit 142 comprising: at least one component 184 that is energized during penetration (col. 7, lines 26-35) to assist in penetrating tissue (e.g. by ablation).

As to claim 37, Cosman discloses a rigid penetrator 184, the energized component being positioned on a forward end of the penetrator (since the entire penetrator 184 is an electrode), the tissue resident conduit being in operative and removable connection with the penetrator so that the penetrator can be removed from penetrated tissue while the tissue resident conduit remains within the penetrated tissue (col. 7, lines 47-50).

Note that the penetrator is inserted into the tissue resident conduit 142 and is capable of being removed due to the feature of the invention where various types of stylets may be interchanged depending on the user's preference. Note that penetrator 184 (e.g. cannula) is generally within the penetrated tissue and remains (col. 8, lines 39-47), and

is capable of the required functional language of the claim. In an alternative interpretation, the rigid penetrator may be element 142 and the tissue resident conduit may be element 184.

As to claim 39, Cosman discloses the penetrator is positioned within the conduit during penetration (see arrows of Fig 3).

As to claim 40, Cosman discloses the tissue resident conduit is positioned adjacent the penetrator during penetration (since when the penetrator is inside the conduit, the penetrator is also adjacent the conduit).

As to claim 41, Cosman discloses the tissue resident conduit is flexible (col. 7, lines 59-64).

As to claim 43, the tissue resident conduit of Cosman is a catheter since it's a tube inserted into the body and is capable of keeping a passage open.

6. **Claims 34, 37 and 38** are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al. (USPN 5,599,345).

As to claim 34, Edwards discloses a device for inserting a tissue resident conduit 16 comprising: at least one component that is energized during penetration to assist in penetrating tissue since it is an electrode (col. 6, lines 50-57).

As to claim 37, Edwards discloses a rigid penetrator 20, the energized component being positioned on a forward end of the penetrator (see Fig 3), the tissue resident conduit being in operative and removable connection with the penetrator so that the penetrator can be removed from penetrated tissue while the tissue resident conduit

remains within the penetrated tissue since the penetrator 20 is capable of penetrating tissue along with tissue resident conduit and has a slidable movement along the tissue resident conduit (col. 7, lines 34-41). Note that the penetrator 20 is considered to be rigid since it inherently has some level of rigidity.

As to claim 38, Edwards discloses the penetrator comprises an axial passage therethrough (see Fig. 3) in which the tissue resident conduit is capable of being positioned during penetration.

7. **Claims 51-53** are rejected under 35 U.S.C. 102(b) as being anticipated by Saadat et al. (USPN 6,120,520).

As to claim 51, Saadat discloses in Figs. 5 and 6 a non-coring needle comprising a penetrating member 61 (the needle is the penetrating member, col. 6, lines 2-3), a forward end of the penetrating member comprising a forward extending section comprising at least two points spaced from each other and being adapted to pierce tissue. Note that the term "two points" is extremely broad and does not necessarily require two sharpened points in the manner of Fig. 11e of Applicant's drawings. Two points may be broadly interpreted as having an arbitrary two points on the forward section of the penetrating member. Furthermore, needles with two sharpened points are known in the art (see Citation of Pertinent Art below).

As to claim 52, Saadat discloses an actuator 26 (e.g. controller) to energize at least a portion of the needle (e.g. electrodes 42a-b) to facilitate penetration (col. 7, lines 44-50).

Note that language "to facilitate penetration" is functional language that the needle of Saadat is capable of since it emits RF energy.

As to claim 53, Saadat inherently discloses at least a portion of the forward end of the penetrating member is non-cutting so that coring does not occur upon penetration of the tissue since the needle is non-coring (col. 6, lines 2-3).

8. **Claims 51 and 54** are rejected under 35 U.S.C. 102(b) as being anticipated by Ayres. (USPN 3,906,932).

As to claim 51, Ayres discloses a non-coring needle in Fig. 2 (abstract) comprising a penetrating member 10a (the needle is the penetrating member), a forward end of the penetrating member comprising a forward extending section comprising at least two points (bottom-left corner of 16a and bottom-right corner of 18a) spaced from each other and capable of piercing tissue.

As to claim 54, the needle of Ayres has the two points positioned such that they are capable of stabilizing tissue for penetration.

9. **Claims 55-56** are rejected under 35 U.S.C. 102(b) as being anticipated by Cohen (USPN 4,832,048).

As to claim 55, Cohen discloses a blunt needle (Fig. 3) comprising at least one effector 30 that does not readily penetrate tissue (e.g. when the power is off) and at least one actuator 52 that when energized enables the needle to readily penetrate tissue. Note that Applicant states "the term 'needle' refers to relatively slender instruments that can

be used to penetrate, and includes instruments having a passage or channel for introducing material into or removing material from the body parenterally. In common language, needles tend to be sharp and rigid whereas catheters are non-cutting and usually soft and flexible. With energy assistance, the distinction blurs because soft materials (such as the materials used in catheters) can cut. Therefore needles encompass as a subset both needle-catheter systems such as used for vascular access and catheters. Needles in this context can also be solid, have multiple independent or communicating passages, and be made of various materials and construction styles." Thus the distal end of the device of Cohen is considered to be a needle since it meets Applicant's definition.

As to claim 56, Cohen discloses a conduit 48 such that fluid can be delivered to the tissue or material removed from the tissue (col. 4, lines 8-12; col. 5, lines 7-10).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Stewart discloses a split tip needle for a biopsy instrument (USPN 3,175,554).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN LEE whose telephone number is (571)270-1407. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571)-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. L./ 1/22/2010
Examiner, Art Unit 3739

/Linda C Dvorak/
Supervisory Patent Examiner, Art
Unit 3739